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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/488,229	01/20/2000	Edward H. Cully	MP/140A	4139
7590	09/30/2004		EXAMINER	
Wayne D House W L Gore & Associates Inc 551 paper Mill Road P O Box 9206 Newark, DE 19714-9206			BUI, VY Q	
			ART UNIT	PAPER NUMBER
			3731	
			DATE MAILED: 09/30/2004	

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/488,229	CULLY ET AL. <i>On</i>
	<b>Examiner</b>	<b>Art Unit</b>
	Vy Q. Bui	3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 30 June 2004.
- 2a) This action is **FINAL**.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above claim(s) 8,20,21,26,27,34,40,41,46 and 47 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-7,9-19,22-25,28-33,35-39 and 42-45 is/are rejected.
- 7) Claim(s) 35 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
    - a) All    b) Some \* c) None of:
      1. Certified copies of the priority documents have been received.
      2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
      3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_.

**DETAILED ACTION*****Election/Restrictions***

Applicant's election without traverse of Species I (Fig. 1A-1H) in Paper No. 6 is acknowledged and now made final.

Claims 8, 34, 47 (Fig. 4, species 4), 20-21(Fig. 3, species 3), 26-27, 40-41, 46 (Fig. 2, species 2) are withdrawn from further consideration.

***Claim Objections***

Claim 35 is objected to because of the following informalities: "claim 23" should have been – claim 32--. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 15 recites the limitation "the thermoplastic fluoropolymer" in line 1, however, there is no mention or recitation of this limitation in the related previous claims 1, 11 and 12. There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 32-33, 35-39 are rejected under 35 U.S.C. 102(e) as being anticipated by LEOPOLD et al (6,352,561).

As to claims 32-33, 35-39, LEOPOLD (Fig. 3; col. 11, ll. 4-65) discloses a prosthesis comprising nitinol stent 126 and cover 124 of ePTFE joined together by adhesive FEP, which adhesive can render the cover 124 non-porous (col. 11, ll. 39-44) and further more, LEOPOLD (Fig. 15-17; col. 19, ll. 15-47) discloses the prosthesis including protruding means 716/716' for anchoring the device to the deployment site.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 1-7, 9-12, 13-19, 22-24, 35 are rejected under 35 U.S.C. 103(a) as being obvious over LEOPOLD et al (6,352,561) in view of LAU et al. (5,735,893).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art

only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

As to claims 1-7, 9-11, 13-19, 22-24, 35, LEOPOLD (Fig. 3; col. 11, ll. 4-65) discloses nitinol stent 126 and cover 124 of ePTFE of a thickness about 0.1 mm (col. 11, ll. 45-47) joined together by adhesive FEP, which adhesive can render the cover 124 non-porous (col. 11, ll. 39-44) and substantially every limitation in the claims, except for the stent has the stent foreshortens less than 10 % when expanded. LAU (Fig. 4, 13-14; col. 3, ll. 3-7) discloses a stent having interconnecting member 13 for avoiding foreshortening of the stent. In view of LAU, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify or construct LEOPOLD stent to have outwardly protruding apices and to have a foreshortening percentage less than about 10%.

As to claim 12, the coating processes as recited in the claim are well known coating processes in the art. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the processes to make a coating on the covering.

As to claim 25, LEOPOLD discloses substantially every limitation in the claims, except for the thickness of the cover 124 less than 0.05mm. However, ePTFE cover of thickness less than 0.05mm for low profile of a stent-graft during deployment is well known in the art. It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the cover of a thickness less than 0.05mm for low profile during the stent-graft deployment.

As to claims 28-31 and 42-45, LEOPOLD discloses substantially every limitation in the claims, except for the liquid impermeability of the cover as recited in the claims. It is well known to make a cover of a biliary stent-graft impermeable to bile fluid and the bubble test pressures as recited in the claims are just another indicator to express the inherent characteristics of a conventional cover for a biliary stent-graft.

#### ***Response to Amendment***

The amendment filed on 6/30/2004 under 37 CFR 1.131 has been considered but is ineffective to overcome LEOPOLD et al.-'561 reference as indicated above.

Claim 15 is rejected as indicated above under the second paragraph of 35 U.S.C. 112 because there is no antecedent basis in the claim or related preceding claims 1, 11 and 12. Claim 15 should have been dependent to claim 14 instead of claim 12.

LEOPOLD-'561 discloses protruding means as recited in the claims as indicated in 102(e) rejection above.

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The 103(a) rejection remains as presented above because the claimed subject matter in the present application was disclosed in the parent case 09/235,460, therefore, the effective filing date of the present invention was the same as the parent case 09/235,460, which parent case was filed on 1/22/1999 and was before November 29, 1999. Consequently, a showing that the subject matter of the LOPOLD-'561 reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person can not overcome the 103(a) rejection.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vy Q. Bui whose telephone number is 703-306-3420. The examiner can normally be reached on Monday-Tuesday and Thursday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T Nguyen can be reached on 703-308-2158. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
\_\_\_\_\_  
09/22/2004

Vy Q. Bui  
Primary Examiner  
Art Unit 3731